

### REMARKS

Claims 1-7, 9, and 13-29 are pending. Claims 1-6 and 13-27 are withdrawn from consideration in the present application and are canceled herein without prejudice. Claim 7 is amended herein to more clearly set forth aspects of the invention. Accordingly, amended claim 7 and dependent claims therefrom are under consideration.

Any amendment, however, is not to be construed as abandonment of any subject matter of the originally filed application. Accordingly, it is to be understood that Applicant reserves the right to reintroduce subject matter deleted from the application by the foregoing amendments and to file one or more divisional, continuation, and/or continuation in part applications directed to such subject matter.

Support for the amendments to the claims is found throughout the specification and in the original claims. Specifically, support for the amendment to claim 7 is presented, for example, in original claims 7 and 12 and at page 2, lines 25-27 and in Example 3 of the specification. No issue of new matter is introduced by the amendments to the claims.

### Rejections under 35 USC § 112

Claims 7, 9, 28, and 29 are rejected under 35 USC § 112, second paragraph, for alleged indefiniteness. Claim 7 is amended herein to clarify that the antibody specifically interacts with a CDCP1 polypeptide comprising residues 30-667 of SEQ ID NO: 1. In view of the amendment to the claims, the rejection of claims 7, 9, 28, and 29 is respectfully traversed.

Reconsideration and withdrawal of the rejection of claims 7, 9, 28, and 29 under 35 USC § 112, second paragraph, is, therefore, deferentially requested.

Claims 7, 9, 28, and 29 are rejected under 35 U.S.C. § 112, first paragraph, for an alleged lack of enablement. Claim 7 is amended herein to clarify aspects of the claim. More specifically, instant claim 7 is directed to a method for the treatment of ovarian cancer comprising administering a therapeutically effective amount of an antibody which specifically interacts with a CDCP1 polypeptide comprising residues 30-667 of SEQ ID NO: 1. In view of the support presented in the specification for the claimed method and additional corroborative evidence presented in Dr. Mason's Declaration submitted herewith, Applicant asserts that the instant claims are enabled. That being the case, the rejection of claims 7, 9, 28, and 29 under 35 U.S.C. § 112, first paragraph, is traversed.

The Examiner acknowledges that the evidence presented in both the as-filed application and Dr. Mason's Declaration filed July 5, 2007 demonstrates that CDCP1 is detectable on ovarian cancer cells and the CDCP1 antibody of the claims binds to ovarian cancer cells. The Examiner also recognizes that recruitment of other molecules or use of a conjugated antibody would provide a therapy to induce cell death, and thus an effective treatment for ovarian cancer. The Examiner maintains, however, that sufficient support for a method wherein the unconjugated anti-CDCP1 antibody is used as an ovarian cancer therapy has allegedly not been presented in either the as-filed application or the Declaration of July 5, 2007.

Responsive thereto, Applicant submits a second Declaration executed by Dr. Mason, wherein data are presented demonstrating that binding and/or internalization of the antibody/polypeptide complex comprising unconjugated anti-CDCP1 antibody leads to cell death. As detailed in the Declaration and shown in Appendix B, a CDCP1-specific antibody specific for the extracellular domain of CDCP1 mediates lysis of the human ovarian tumour cell line SKOV-3 in an antibody-dependent cellular cytotoxicity (ADCC) assay. Moreover, CDCP1 antibody mediated lysis of SKOV-3 cells occurs in an antibody dose-dependent manner. The efficacy of the CDCP1-specific antibody was also examined in a widely recognized animal model of experimental metastasis. This model system is explained in detail in the Declaration and experimental results pertaining to the system as adapted with respect to detectable cells that express CDCP1 and antibody mediated targeting of such cells are shown in Appendices C and D. In short, administration of the CDCP1 antibody to animals expressing detectable CDCP1 expressing cells leads to a dramatic reduction in detectable CDCP1 expressing cells at the site of metastasis as observed using *in situ* bioluminescent imaging technology. Manual quantitation of tumor metastases performed *post mortem* confirmed these results. In sum, the data presented in the Declaration demonstrate that a CDCP1-specific antibody mediates lysis of ovarian cancer cells *in vitro* and drastically decreases tumor growth and/or establishment *in vivo* of cells that express CDCP1. Based on these findings, a skilled practitioner would appreciate that an antibody specific for CDCP1 would target the CDCP1 present on cancerous cells and be an effective therapeutic agent *in vivo*.

In view of the arguments presented herein and the assertions presented in Dr. Mason's Declaration submitted herewith, the rejection of claims 7, 9, 28, and 29 under 35 U.S.C. § 112,

first paragraph, is respectfully traversed. In light of the above, reconsideration and withdrawal of this rejection are, therefore, respectfully requested.

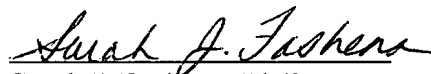
### ***Fees***

No additional fees are believed to be necessitated by this amendment. However, should this be an error, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment or to credit any overpayment.

### ***Conclusion***

It is submitted, therefore, that the claims are in condition for allowance. No new matter has been introduced. From the foregoing, further and favorable action in the form of a Notice of Allowance is believed to be next in order, and such action is earnestly solicited. In the event that there are any questions concerning this amendment, or application in general, the Examiner is respectfully urged to telephone the undersigned so that prosecution of this application may be expedited.

Respectfully submitted,



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Enclosure: Request for Continued Examination  
Dr. Mason's Declaration  
Appendix A: Dr. Mason's Curriculum Vitae  
Appendix B: Figure 1  
Appendix C: Figure 2  
Appendix D: Figure 3  
Appendix E: References cited in Dr. Mason's Curriculum Vitae